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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,841	09/30/2002	Susanne Brakmann	B1180/20005	5272
3000 7590 07/17/2008 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOV, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212				
EXAMINER ALEXANDER, LYLE				
ART UNIT 1797		PAPER NUMBER		
NOTIFICATION DATE 07/17/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary

Application No.

10/089,841

Applicant(s)

BRAKMANN ET AL.

Examiner

Lyle A. Alexander

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 27, 28 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 27-28 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters (USP 4,299,920) in view of Elkins (USP 4,441,793) together further in view of Muramatsu (USP 6,645,434).

See the appropriate paragraphs of the 2/15/08 Office action for the teachings of the references combined above.

The 5/15/08 amendments add the limitations that the silicone rubber has a thickness from 0.5mm to 4mm, the sample volume is from 1nl to 10 microliters and "variations of positions of the sample ... less than 250 microns ...".

The court decided *In re Boesch* (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. Variations in the thickness of a layer, the sample volume and the variations in the position of the sample reservoir are all result effective variable with well known and expected results. It would be desirable to make the compartment layer as thin as possible, such as from 0.5 to 4mm, to minimize the material used and the manufacturing cost. It would have been desirable to use a minimal amount of sample, such as from 1 nl to 10 microliter, to preserve the sample for further testing and minimize the amount of reagents required to perform the analysis. It would have been desirable to place the sample reservoir in the same position, such as

the claimed variations of positions of the sample ... less than 250 microns, to create a uniform product that can be used with automated analyzers.

It would have been within the skill of the art to further modify Peters (USP 4,299,920) in view of Elkins (USP 4,441,793) together further in view of Muramatsu (USP 6,645,434) and give the silicone rubber a thickness from 0.5mm to 4mm, a sample volume from 1nl to 10 microliters and "variations of positions of the sample ... less than 250 microns ..." as optimization of a result effective variable and to gain the above advantages.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters (USP 4,299,920) in view of Elkins (USP 4,441,793) together further in view of Muramatsu (USP 6,645,434) as applied to claims 17-23 and 29-36 above, and further in view of Brown (USP 6,037,168).

See Peters (USP 4,299,920) in view of Elkins (USP 4,441,793) together further in view of Muramatsu (USP 6,645,434) supra.

These references do not teach an upper layer having channels that comprise fluid lines. Brown also teaches a device that is comprised of an upper layer (24) with holes (26) that form wells when placed on another, lower base layer (22). The upper layer of Brown may also include channels that connect the wells. This allows for the exchange of fluids between the wells (column 14, lines 14-28). It would have been obvious to combine the channels of Brown with the combined device of Peters and Elkins. One would add the channels to the elastomeric layer in order to allow for the exchange of fluids between wells as suggested by Brown.

Response to Arguments

Applicant's arguments filed 5/15/08 have been fully considered but they are not persuasive.

Applicants' state the cited prior art fails to teach the limitations that the silicone rubber has a thickness from 0.5mm to 4mm, the sample volume is from 1nl to 10 microliters and "variations of positions of the sample ... less than 250 microns ...". These amendments were newly submitted and have been addressed in the above new grounds of rejection.

Applicants' 6/24/08 Declaration filed under 37 C.F.R. 1.132 has been considered but was not convincing. The substance of the Declaration lacked factual evidence and was directed to the opinion of Dr. Brakmann.

The court decided : In re Beattie, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992) (declarations of seven persons skilled in the art offering opinion evidence praising the merits of the claimed invention were found to have little value because of a lack of factual support); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991) (conclusory statements that results were "unexpected," unsupported by objective factual evidence, were considered but were not found to be of substantial evidentiary value). Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application. In re Brandstadter, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973).

While Dr. Brakmann's opinion is held in high esteem, the lack of factual evidence made the Declaration not convincing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1797

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Primary Examiner, Art Unit 1797